Atty Dkt. No.:GUID-009 USSN: 09/118,132

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A device for manipulating and positioning an organ, said device comprising:

<u>an (a) at least one</u> inflatable annular member having <u>an a central</u> opening <u>passing</u> therethrough and an organ contacting surface;

- (b) a vacuum distribution element operatively associated with said inflatable annular member; and
- (c) a positioning element comprising a lumen passing through at least a portion thereof, said positioning element connected to said inflatable member and sealing one end of said opening, said lumen configured to be coupled to a vacuum source and fluidly communicate with said opening through and said inflatable annular member, wherein said positioning element is configured to position said inflatable annular member and deliver negative pressure to a surface of the organ via said lumen and said opening, when said organ contacting surface contacts provide a vacuum to the organ.
 - 2. (Original) The device according to claim 1, wherein the organ is a beating heart.
- 3. (Currently Amended) The device according to claim 1, wherein one or more seams of said inflatable annular member is positioned on the interior of said inflatable annular member.
- 4. (Original) The device according to claim 1, wherein the organ contacting surface comprises an atraumatic, compliant material.
- 5. (Canceled) Please cancel claim 5 without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.
- 6. (Original) The device according to claim 4, wherein said atraumatic, compliant material is configured to conform to, and diffuse suction exerted on, the organ.
- 7. (Currently Amended) The device according to claim 1, <u>further comprising a wherein said</u> vacuum distribution element <u>fluidly interconnecting said lumen and said opening, said vacuum</u>

USSN: 09/118,132

<u>distribution element being is configured to diffuse the negative pressure applied to the surface of suction exerted on the organ.</u>

- 8. (Currently Amended) The device of claim 7, -according to claim 1, wherein said vacuum distribution element is selected from the group consisting of foam, gel, fabric, gauze, and material of the type conventionally used in neuro sponges.
- 9. (Currently Amended) The device of according to claim 1, further comprising an attachment element interconnecting said wherein said inflatable annular member and said is coupled to said positioning element, wherein said attachment element fluidly seals a connection of said lumen with said opening and allows limited freedom of movement of said inflatable member with respect to said positioning element, such that when said inflatable member is engaged with the surface of the organ, normal movements of the organ are permitted by movement of said inflatable member with respect to said positioning element with an attachment means.
- 10. (Currently Amended) The device of according to claim 9, wherein said attachment element means comprises a flexible plastic.
- 11. (Currently Amended) The device of according to claim 9, wherein said attachment element comprises means is comprised of a series of segments.
- 12. (Currently Amended) The device of according to claim 9, wherein said attachment element means comprises a flexible linkage mechanism.
- 13. (Currently Amended) The device <u>of according to claim 9</u>, wherein said attachment <u>element</u> means comprises a ball and socket mechanism.
- 14. (Currently Amended) The device of according to claim 9, wherein said attachment element means is configured to allow sufficient vertical and lateral movement of said inflatable annular member, when engaged with the organ, where the organ is a beating heart, and when said positioning element is held relatively stationary, so as not to reduce negative effects on hemodynamics of the beating heart.

USSN: 09/118,132

15. (Currently Amended) The device of according to claim 1, wherein said positioning element further comprises a spring to enable axial movement of said inflatable annular member relative to said positioning element.

- 16. (Currently Amended) The device of according to claim 1, further comprising an inflation line configured to be connected with a source of fluid, and fluidly connected to said inflatable member, said inflation line being independent of a fluid pathway established by said lumen wherein said device is capable of being retained inside a sheath.
- 17. (Currently Amended) The device of according to claim 16, wherein inflatable member is resiliently deformable to a deflated configuration by application of negative pressure through said inflation line said retained device is deflated.
- 18. (Currently Amended) The device of according to claim 16, 1, wherein said inflatable member is inflatable by delivery of a pressurized fluid through said inflation linedevice is inflated with a substance selected from the group consisting of gas, saline, water, contrast solution, and combinations thereof.
- 19. (Currently Amended) The device according to claim 17, 1, further comprising a sheath configured to receive said inflatable member in said deflated configuration—wherein said device is capable of manipulating and positioning the organ absent clinically relevant hemodynamic instability.

Claims 20 – 22 (Canceled) – Please cancel claims 20-22 without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

- 23. (Currently Amended) The <u>device of claim 1, system according to claim 20</u>, further comprising a securing means for securing said device to a stationary object.
- 24. (Canceled) Please cancel claim 24 without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.
 - 25. (Currently Amended) A method of manipulating and positioning an organ, said method

Atty Dkt. No.:GUID-009 USSN: 09/118.132

comprising:

(a) introducing a <u>deflated member of a</u> device into a body cavity; , wherein said device comprises:

- (i) at least one inflatable annular member having a central opening and an organ contacting surface,
- (ii) a vacuum distribution element operatively associated with said inflatable annular member, and
- (iii) a positioning element comprising a lumen coupled to a vacuum source and said inflatable annular member, wherein said positioning element is configured to position said inflatable annular member and provide a vacuum source to the organ, and
 - (b) inflating the member to an inflated configuration said device;
 - (e) contacting the organ with the inflated member said device; and
- (d) applying a vacuum to the organ through an opening in the inflated member, while maintaining the inflated member in the inflated configuration, to create an intimate engagement between the organ and the inflated member; and

moving the inflated member, to manipulate or position said device; whereby the organ is manipulated and positioned with said device.

- 26. (Currently Amended) The method of according to claim 25, wherein the deflated member said device is introduced into the said body cavity through an opening created by one of a the group consisting of sternotomy, mini-sternotomy, thoracotomy, mini-thoracotomy and a port.
- 27. (Currently Amended) The method of according to claim 25, wherein the deflated member is encased in a said device is introduced into said body cavity through a sheath during said introducing.
- 28. (Currently Amended) The method of according to claim 25, wherein the pressurized fluid is said device is inflated with a substance selected from one of the group consisting of gas, saline, water, contrast solution, and combinations thereof.
- 29. (Currently Amended) The method of according to claim 25, wherein the said contacted organ is a beating heart.

USSN: 09/118,132

30. (Currently Amended) The method of according to claim 25, further comprising diffusing a flow of the vacuum through said opening to the organ-wherein said vacuum exerted on the organ is diffused.

- 31. (Canceled) Please cancel claim 31 without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.
- 32. (Canceled) Please cancel claim 32 without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.
- 33. (Original) The method according to claim 25, further comprising securing said device to a stationary object.
- 34. (Original) The method according to claim 25, further comprising performing a coronary artery bypass procedure on the organ.
- 35. (Original) The method according to claim 25, wherein said device is manipulated and positioned absent clinically relevant hemodynamic instability.
 - 36. (Original) A kit for manipulating and positioning an organ, said kit comprising:
 - (a) at least one device according to claim 1; and
 - (b) instructions for using said device to manipulate and position the organ.
 - 37. (Original) The kit according to claim 36, comprising a plurality of devices.
- 38. (Original) The kit according to claim 36, further comprising at least one sheath for delivering said device into a body cavity.
- 39. (Original) The kit according to claim 36, further comprising at least one securing means for securing said device to a stationary object.

USSN: 09/118,132

40. (Original) The kit according to claim 36, further comprising at least one regulator for regulating a flow of vacuum.

41. (New) A device for manipulating and positioning an organ, said device comprising: an inflatable member having an opening passing therethrough and an organ contacting portion surrounding a distal end of said opening;

a first lumen connected to a proximal end of said opening and forming a fluid seal with said proximal end, said first lumen configured to deliver negative pressure through said opening;

a second lumen fluidly connected to said inflatable member and not fluidly connected with said opening; and

a positioning element connected to said inflatable member.

- 42. (New) The device of claim 41, further comprising an attachment element interconnecting said inflatable member and said positioning element, wherein said attachment element allows limited freedom of movement of said inflatable member with respect to said positioning element, such that when said inflatable member is engaged with the surface of the organ, normal movements of the organ are permitted by movement of said inflatable member with respect to said positioning element.
- 43. (New) The device of claim 41, further comprising a vacuum distribution element fluidly interconnecting said lumen and said opening, said vacuum distribution element being configured to diffuse the negative pressure applied to a surface of the organ through said distal end of said opening.